

### **REMARKS**

This responds to the Office Action dated on August 27, 2007. No claims are amended, cancelled, or added. As a result, claims 1-32 remain pending in this patent application.

#### **Request for Telephonic Interview**

Even though no claims are being amended in this response, it is being filed with a Request for Continued Examination and a Supplemental Information Disclosure Statement. In the event that this response does not result in allowance of all claims, then Applicant respectfully requests a telephonic interview with Applicant's representative, Suneel Arora, to further discuss the rejection or any new grounds of rejection, and to discuss any possible claim amendments that would expedite examination and allowance of this case.

#### **§102 Rejection of the Claims**

Claims 1-9, 15, 17-22 and 30-31 were rejected under 35 U.S.C. § 102(b) for anticipation by Snell et al. (U.S. Patent No. 5,431,691, hereinafter "Snell"). Applicant respectfully traverses this rejection.

Before delving into the grounds for traversal, it may be useful to revisit a particular problem that can be addressed by the claimed invention, as pointed out by Applicant's specification:

As technology used in implantable medical devices advances, the devices will be able to collect data from multiple leads and multiple sensors from multiple locations. They also will detect events occurring from such multiple sources. Potentially, this results in a large amount of data to be collected by the implantable device and transmitted to the external device. Additionally, the data may be collected from different types of sensors at different times and/or sampling rates, or processing may be done on the collected data by the implantable device before the data is transmitted to an external device. Thus, the relative timing between the events and the data as displayed at the external device is often different from the relative timing of the events and data as they actually occur.

The large amount of data coming from various sources complicates the task of reconstructing the information for a display while preserving the correct timing relationship among the data and markers.

(Published Application ¶¶ 6-7.) Applicant has disclosed how this complicated data management and timing problem can be solved using a practical clock circuit that generates readable values that roll over every few minutes—this is a highly important advantage in a compact, low power consumption implantable medical device implementation, in that it avoids a need for a higher power consumption clock circuit indicative of absolute time, which would also likely require more integrated circuit space to implement. Applicant’s disclosure teaches how event timestamps can be created using such an advantageous compact, low power clock circuit implementation that rolls over every few minutes, so that the events can be properly re-aligned with respect to each other and time when communicated to an external device for display. This, too, is valuable, since a physician needs accurate alignment and display of such cardiac or other events in order to make a proper diagnosis of the patient’s condition.

With this in mind, it is important to point out that Applicant cannot find in the cited portions of Snell any disclosure of a “clock circuit that generates readable values, wherein the clock circuit and the readable values roll over every few minutes,” as similarly recited or incorporated in the present claims. The Office Action asserts:

Regarding claims 1-3, 17-19 and 21, Snell discloses an implantable medical device that has an input, a sampler circuit, a clock circuit, a circular rollover buffer that records and rollover over a set time, a controller that puts the data into memory, includes time stamp and transmits the data to an external device when the buffer is full making the process happen in substantially real time (Col. 14; Col. 16, ll. 24-59.)

(Office Action ¶ 4.) However, the cited portions of Snell merely state:

. . . R-waves) and providing stimulation pulses (A-pulses and/or V-pulses) to invoke paced cardiac activity. The operating characteristics of the pacemaker 16 can be noninvasively programmed by way of command signals received over telemetry link 70, which command signals are received from a telemetry head 74 connected to the APS-II/MTM processing circuits 76 by way of a connection cable 77. The command signals are generated within the APS-II/MTM processing circuits 76 as a function of operating commands received by way of a touch

sensitive screen 78. That is, an APS-II/MTM operator selects a desired command by touching a designated area on the touch screen 78, which designated area is defined by a particular pattern displayed on a display screen 80. Advantageously, the touch screen 78 overlays the display screen 80 so that all one need do to make a command selection is to touch the screen at the area indicated on the display for the desired command.

*The pacemaker 16 is also capable of sending operating data and measured data over the telemetry link 70 to the telemetry head 74. Such measured data includes event/rate data as described more fully below, which event/rate data is determined by monitoring particular changes in state of the pacemaker state logic 42. The telemetry head 74 preliminarily processes such data and forwards it on to the APS-II/MTM processing and memory circuits 76. Data received at the APS-II/MTM circuits 76 may be displayed on the display screen 80, printed on a printer 82, and/or stored within the memory elements of the APS-II/MTM circuits 76 for subsequent retrieval and display. Alternatively or conjunctively, data received at the APS-II/MTM circuits 76 may be transmitted over an appropriate data channel 84 to a desired external device, such as a modem, an X-Y plotter, a tape or disk drive, a personal computer, or other peripheral device.*

Operation of the APS-II/MTM processing and memory circuits is controlled by way of a program cartridge 86 that is detachably connected to the processing and memory circuits 76. Removable program cartridge 86 thus advantageously allows the operating characteristics of the APS-II/MTM device to be easily upgraded to include new features and to properly interface with new pacemakers, as new features and new pacemakers are developed. Such upgrading can occur at minimal cost because all that is required is a new program cartridge 86, rather than a whole new analyzer-programming system 20, as has been required in the past. The present invention, relating to a method and system for recording and reporting the distribution of pacing events over time, is facilitated through the use of a such new program in a new program cartridge 86.

FIG. 4 illustrates a housing 90 within which the APS-II/MTM system components are housed. In accordance with one embodiment, all of the circuits of the APS-II/MTM processing circuits and memory 76, including the printer 82, the display screen 80, the touch screen 78, and the program cartridge 86, are housed within the housing 90. The telemetry head 74 is coupled to the housing 90 by way of cable 77. As seen in FIG. 15, a CRT screen 92, over which touchscreen 78 is laid, provides a readily visible and accessible means for viewing displays and selecting commands. Similarly, the printer 82 provides a paper copy 94 of that which is displayed on the screen of the CRT 92, or other desired information, as selected by the various commands available through touching the touchscreen. The telemetry head

As indicated above in Table 1, there are some eighteen states associated with the operation of the pacemaker 16 when configured for operation in a dual-chamber mode. Three of the eighteen defined states relate directly to cardiac activity that occurs in the atrium. These three atrial states are: (1) atrial pulse (A-pulse), referred to as "APW" or state 0 in Table 1; (2) sensed P-wave, referred to as "SIPW" or state 3 in Table 1; and (3) sensed P-wave during the Maximum tracking interval, referred to as "LIPW," or state E in Table 1. Similarly, two of the eighteen defined states relate to cardiac activity that occurs in the ventricle. These two ventricle states are: (1) ventricular stimulation pulse (V-pulse), referred to as "VPW," or state 6 in Table 1; and (2) sensed R-wave, referred to as "SIRW," or state 7 in Table 1. Advantageously, the changing of the state machine 42 from one state to another state signals the occurrence of a particular event. Selected state changes associated with the state machine 42 may thus be considered as "pacing events." Such pacing events may also be considered as one of the outputs of the state machine 42, and such events are identified generically in FIG. 5 as a data parameter 122. *In accordance with the present invention, such "pacing events are recorded in sequence as they occur, or at a specified sampling rate, and as a function of the type and rate of event that occurred in a "circular" buffer memory 120. Note that a "circular" buffer memory is simply a designated portion of the pacemaker memory 62 wherein the data parameters are stored in such a way that they can be retrieved in the same order in which they were stored, and wherein the newest or most recent data always replaces the oldest or least recent data. Thus, the circular buffer memory 120 always contains the last n pacing events stored therein, where n is the storage capacity of the circular buffer memory 120.*

(Snell at Col. 14; Col. 16, ll. 24-59 (emphasis added).) Thus, Snell apparently merely discloses a circular memory buffer for storing events—not a clock circuit that generates readable time values, wherein the readable values roll over every few minutes, as similarly recited or incorporated in the present claims. This claimed element is missing entirely from the cited portions of Snell. The Office Action goes on to assert:

The controller further generates markers that include a marker code, a timestamp and additional data (e.g., Figs. 9-20; Col. 25, lines 35-57).

(Office Action ¶4.) However, FIGS. 9-20 of Snell cited by the Office Action appear to merely show various external programmer screen displays, including screen displays of certain events. The text portion of Snell cited by the Office Action merely states:

Still referring to FIG. 9 in the preferred embodiment, a broad light line 222 may appear in the center of the Event Record screen 186. This broad light line 222 provides a reference marker for scrolling and otherwise examining the data. A bold line 224 is used to mark when a magnet is applied to the pacemaker. The mode of the pacer up to the point of the bold marker line 224, using the conventional three letter code, is indicated near the top of the marker line at 226. As indicated above, the presence of a magnet suspends the collection of the Event Record data. Given that time sequence is an essential feature of the Event Record, the bold or heavy marker 224 thus identifies when data collection is halted, even if only transiently. Thus, a patient may sense something abnormal, such as an intermittent palpitation. The patient may be instructed by the physician to place a magnet over the pacemaker when the palpitations are experienced. This results in a mark being placed in the Event Record at that time. The patient may then go to the physician's office where the Event Record data may be retrieved directly from the pacemaker and examined in order to determine the events that led up to the palpitations.

(Snell at Col. 25, lines 35-57.) Applicant respectfully submits that this cited portion of Snell merely pertains to using a reference marker on an external programmer display for scrolling through and otherwise examining displayed data—nothing in this cited portion of Snell indicates any relevance to the claimed controller, which is clearly recited as being part of the implantable medical device, and which generates a timestamp of when the detected event occurred referenced with respect to the clock circuit time window of the clock circuit in the implantable medical device that rolls over every few minutes, as discussed above.

To recap, Applicant respectfully submits that the cited portions of Snell appear to fail to disclose, among other things: (1) a clock circuit, in an implantable medical device, that generates readable values that roll over every few minutes; (2) a controller circuit, in the implantable medical device, that generates an event marker and associates a timestamp referenced with respect to a clock circuit time window of a clock circuit that rolls over every few minutes; and (3) an external device that can use such a timestamp to properly align the event marker information on an external display, as similarly recited or incorporated in the present claims. Therefore, Applicant respectfully submits that no *prima facie* case of anticipation exists with respect to the present claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

1. Claims 10, 16, 23, 29 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Snell et al. (U.S. Patent No. 5,431,691). Applicant respectfully traverses on the grounds that no *prima facie* case of obviousness exists with respect to these claims because all elements are not disclosed, taught, or even suggested by the cited portions of Snell, for the reasons discussed above with respect to the § 102 rejection. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims.

2. Claims 11-14 and 24-29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Snell et al. (U.S. Patent No. 5,431,691) as applied to claims 1-9 and 19-22 above, and further in view of McClure et al. (U.S. Patent No. 6,161,043, hereinafter “McClure”). Applicant respectfully traverses on the grounds that no *prima facie* case of obviousness exists with respect to these claims because all elements are not disclosed, taught, or even suggested by the cited portions of Snell, for the reasons discussed above with respect to the § 102 rejection, even with the addition of McClure as an additional basis of rejection. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims.

Reservation of Rights

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner’s personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in

support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

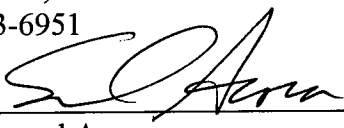
### CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application.

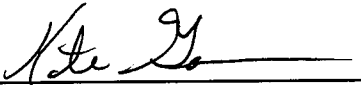
If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

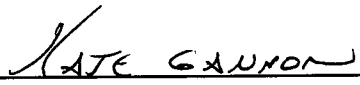
Respectfully submitted,

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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 23 day of October 2007.

  
Name

  
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